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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,882

01/15/2007

Achim Harder

Le A 36379

6821

35969

7590

03/11/2008

Bayer Health Care LLC  
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West Haven, CT 06516

EXAMINER

RAO, SAVITHA M

ART UNIT

PAPER NUMBER

4131

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,882	<b>Applicant(s)</b> HARDER ET AL.	
	<b>Examiner</b> SAVITHA RAO	<b>Art Unit</b> 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/30/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claim 1 is pending and is subject of this office action.

#### ***Information Disclosure Statement***

Receipt is acknowledged of the Information Disclosure Statement filed 09/30/05.

The Examiner has considered the reference cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 provides for the use of compound of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

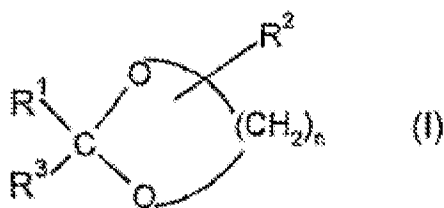
Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 of instant application is drawn towards the use of compounds of formula (I)



for the preparation of

pharmaceuticals with improved permeation of a pharmaceutically active substance across cell and organ barriers with various substituents for  $R^1$ ,  $R^2$ ,  $R^3$  and  $n$ .

For the purpose of the following rejections claim I is being interpreted as method to improve permeation of pharmaceutically active substances across cell barriers by administration of compound of formula (I).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Samour et.al. (US Patent No. 4,861,764)

Samour discloses compounds as described by the formula (I) above of the instant application whereby  $n=2$  or  $3$ ,  $R^1 = C5-C11$ ,  $R^3 = \text{hydrogen}$  and  $R^2 = \text{hydrogen}$  and  $CH_2OH$  (column 4- examples I, II, III; column 5- example IV; column 6- examples VIII-XI; column 7- examples XI to XIV). Samour also describes 1,3-dioxacyclopentanes or 1, 3-dioxacyclohexanes as effective in enhancing the transport of a large number of higher-dose poorly-absorbed drugs through the skin (column 2, lines 25-33) and discloses therapeutic compositions of the same for transdermal administration (column 10, claims 1-12)

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fuhrman Jr. et al. (NPL referenced in applicant supplied IDS).

Fuhrman discloses that dioxolane derivatives have been reported to increase the penetration of lipophilic and hydrophilic drug compounds in vitro (page 200, 2<sup>nd</sup> paragraph) and discloses use of 2-(1-nonyl)-1, 3-dioxolane as described by the formula (I) above of the instant application where  $n=2$ ,  $R^1 = C9$ ,  $R^2 = H$  and  $R^3 = H$  as one of the compounds evaluated for their effect on permeability and dermal accumulation (page 200, 2<sup>nd</sup> and 3<sup>rd</sup> Paragraph, Structure ND in figure 1).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hui et.al.  
(NPL referenced in applicant supplied IDS).

Hui discloses the enhancing effects of 2-n-nonyl-1, 3-dioxolane as described by the formula (1) above of the instant application where  $n=2$ ,  $R^1 = C_9$ ,  $R^2 = H$  and  $R^3 = H$  on penetration of econazole, an antifungal drug, into the deeper layers of the human nail where fungal infection resides (Abstract on page 142).

### ***Conclusion***

Claim 1 is rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 8 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867 and Cecilia Tsang can be reached at 571-272-0567. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/  
Examiner  
Art Unit 4131

/JANET L ANDRES/  
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